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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,747	04/13/2001	Hal Sternberg	BIOT008	4271
24353	7590	02/27/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP			CHOI, FRANK I	
200 MIDDLEFIELD RD			ART UNIT	
SUITE 200			PAPER NUMBER	
MENLO PARK, CA 94025			1616	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,747

Applicant(s)

STERNBERG, HAL

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Examiner requests that Applicant, regardless of whether Applicant amends the claims in response to the rejections below, send by mail a more clear and legible copy. The fax copy is not clearly legible and in some cases completely illegible. In the first claim it appears that either Applicant failed to cross-out some words or the fax copy does not show the line crossing out said words, i.e. line 1, "that does not", line 3, "in an amount".

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as obvious over Segall et al. (U.S. Pat. 5,702,880) or Segall et al. (US Pat. 5,571,801) each in view of EP 0 275 998 or Reed.

Segall et al. disclose a method of administering a blood substitute containing potassium, sodium, magnesium, calcium, chloride, bicarbonate, glucose, Herastarch, wherein the subjects are under anesthesia and are hooked up to an oxygenator falling within the scope of applicant's claims (See Examples and Claims). The compositions and/or procedures will cause a reduction in carbon dioxide levels.

EP 0 275 998 teaches that acidosis can result from reduced levels of oxygen in the tissues and that use of sodium bicarbonate can cause an increase in carbon dioxide pressure which impairs myocardial contractility and undesirable neurological effects and tris(hydroxymethyl)-

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aminomethane buffer mixtures cause thrombophlebitic changes and serous tissue irritation (Pg. 2, lines 10-34). It is taught that amino derivatives of reduced sugars can be used in conjunction with or in place of sodium bicarbonate to combat acidosis (Pg. 3, lines 1-47). It is taught that said sugars can be used in "survival solutions", i.e. aqueous solutions comprising glucose, electrolytes at physiological pH (Pg. 4, lines 16-21). It is taught that administration of said sugars result in elevation of blood pH and a clear decrease in pCO₂ (Pg. 4, lines 23-42, Figure I (showing a dose response decrease in pCO₂ from 40 to 20 mmHg and an increase in pH)).

Reed teaches that increase in pCO₂ leads to lowering of the pH of the blood, i.e. acidosis, which can lead to trauma or death and that because about half of the carbon dioxide dissolved in blood is present as bicarbonate ion, the pH of the blood is directly dependent upon the pCO₂ (Column 1, lines 63-68, Column 2, lines 1-15). A method and apparatus for monitoring and adjusting the concentration of oxygen and carbon dioxide in blood during surgery and other medical procedures, including reducing pCO₂ to avoid acidosis (Columns 7-10).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose reducing the level of CO₂ by at least about 5 mm Hg to reduce the risk of acidosis/acidemia. However, the prior art amply suggests the same as it is known in the art that acidosis and increased blood CO₂ levels can occur during surgery, trauma and/or loss of blood and that drugs or devices can be used to reduce blood CO₂ levels and keep the blood pH at physiological levels. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use drugs or devices to lower blood CO₂ levels as desired, including amounts falling within the claimed ranges, so as to reduce the risk of acidosis and other problems associated with high CO₂ blood levels and acidosis.

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Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection above.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602). Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

February 22, 2004



S. MARK CLARDY
PATENT EXAMINER
GROUP 4200
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